and microbiologically documented infection was similar between groups. Mortality rates were also not significantly different between the two groups.

Conclusions: Adding G-CSF to antibiotic therapy is cost-effective since it shortens the duration of neutropenia, and reduces the duration of antibiotic therapy and hospitalization in pts with high-risk febrile neutropenia.

1463 ORAL

Patients with hematological malignancies experience a higher rate of documented infections than patients with solid tumors after high-dose chemotherapy with autologous peripheral stem cell transplantation

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There are only few reports on infectious complications in different subgroups of patients treated with high-dose chemotherapy (HDCT) and autologous peripheral blood stem cell transplantation (PBSCT). In a retrospective study, we analyzed the data of patients with hematological malignancies (group A, n = 143) or solid tumors (group B, n = 83) treated with HDCT in two german centers. Although febrile neutropenia occurred with the same frequency in both groups (81%), clinically or microbiologically documented infections occurred more frequently in group A (in 40% of patients with febrile neutropenia) than in group B (18%, $p < 0.005$). 74% of all isolated microorganisms were gram-positive. Severe organ infections were rare. There was one infection-related death.

Conclusions: Underlying disease is a determinant of the rate of microbiologically or clinically documented infections after HDCT with autologous PBSCT.

1464 ORAL

A randomized trial comparing the toxicity and the treatment costs of HD-VIC plus PBSC transplantation with or without amifostine (AMI) in patients with solid tumors

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Purpose: Cytoprotection with AMI has demonstrated a reduction of nephro-, neuro- and myelotoxicity. The two-armed study evaluates the toxicity and the costs of HD-VIC ± AMI-treatment.

Methods: 40 pts with different solid tumors were randomized to receive HD-VIC (day $_{1-3}$ Carbo 1500 mg/m^2, Eto 1500 mg/m^2 and Ifo 12 g/m^2 ± AMI 1.5 g per day prior to the application of C and I). Pts were monitored for nephrotoxicity including early urinary marker excretion, mucositis, hematopoetic recovery and frequency of fever and infections. Pts with AMI (n = 19 evaluable; arm A) had a median decrease of creatinine clearance after HD-VIC by 12% compared to 34% to arm B (n = 20 evaluable) ($p = 0.06$). Mucositis III/IV° was 21% in arm B vs. 0% in the AMI-group ($p < 0.001$). Whereas the median no. of days to granulocytes >500/μl was equally in both arms (9.1 vs. 9.8), thrombocyte counts (>20.000/μl) recovered significantly earlier in arm A (10.1 vs. 12.4; $p = 0.02$), resulting in a lower no. of days of thrombocyte transfusions (2.5 vs. 3.5). In addition, the median no. of days with fever >38°C (2.1 vs. 3.9; $p = 0.008$) and days spent in hospital were in favour of pts receiving AMI. A pharmacoeconomic analysis revealed a reduction in costs for supportive care for pts receiving HD-VIC + AMI compared to those treated with HD-VIC alone. This has to be balanced against the drug costs.

Conclusion: This analysis demonstrates that both organ- and hematotoxicity of HD-VIC ctx may be ameliorated by the use of AMI resulting in less mucositis, fever episodes, thrombocyte transfusions and shorter hospital stays.

1465 POSTER

The effect of systematic rHu-erythropoietin (Epoietin alpha) treatment before and during radiotherapy (radio-chemotherapy) in unselected anemic cancer patients: Results of an Austrian multicenter observation study

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Anemia is a common situation in cancer patients, reducing quality of life, tolerance to treatment and likely treatment outcome. Erythropoietin (Epo) is a nontoxic and effective drug for treatment of anemia.

Purpose: The feasibility of systematic administration of Epo before and during radiation (radio-chemotherapy) and it's effect on Hb and quality of life.

Method and Material: One hundred fourty three anemic cancer patients were included in the study of the Austrian Society of Radiation Oncology by 11 centers. Patients recieved three times 300 IU/kg BW per week (Hb < 10 g/dl) subcutanously or 150 IU/kg BW (Hb 10 to 12 g/dl). Start of Epo treatment about 10 days prior to radiation.

Results: Eightyfour percent of patients responded. The median increase of Hb was 0.37 g/dl per week. Thirtyseven percent reached a Hb-level of >14 g/dl. Quality of life was measured at start of EPO treatment and end of radiation according to WHO-criteria. Patients improved in 20.3%, 50.4% remained stable and 27.3% decreased during radiation (+/−chemotherapy). Self assesment resulted in an increase in 19.6%, stability in 32.2% and 44.8% reduction. No relevant adverse reactions to Epo were reported.

Conclusion: The use of EPO under radiation (+/−chemotherapy) is feasible, save and effective. Overall condition may be improved in a significant number of patients, despite aggressive treatment. It's influence on tumor hypoxia and consequently tumor control is an important topic of future research.

1466 POSTER

Non neutropenic infections associated with docetaxel containing chemotherapy in patients with solid tumors

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Purpose: Docetaxel is a potent agent as first line chemotherapy for the treatment of several neoplasias. However, the drug has severe side effects. Lymphopenia, which has been studied only in animals, is one of them. A plethora of infections has been observed recently in lymphopenic, but not neutropenic, patients treated with docetaxel.

Patients and Methods: To detect these of infections all patients receiving the drug during a two-year period were examined prospectively and all non-neutropenic infections were studied. A total of 680 patients, participating in 23 therapeutic protocols, suffering from different neoplasias (breast, non-small cell lung, gastric, pancreatic, uterine cancer cholangrocarcinomas and sarcomas), who had received 2.867 cycles of docetaxel containing regimens were examined.

Results: Fifty three non neutropenic infections were identified and included pneumonias (24), interstitial pneumonias of the pneumocystis carinii type (5), lung abscess (1), bacteremias (2), candida infections (11), herpetic (4), cellulitis (3), cytomegalovirus infection (1) perirectal abscess (1), and urinary tract infection (1). The majority (70%) of the patients was lymphopenic (less than 900/mm3), while all of them had low CD4 (less than 500/mm3), and CD8 (less than 400/mm3) cell counts. The incidence of non neutropenic infections in patients treated with paclitaxel containing regimens and in patients treated with non taxane compounds, during the study period, were calculated for comparison. Paclitaxel had been given in 157 patients with 752 cycles of chemotherapy. They developed 6 non-neutropenic infections ($p = 0.042$), while non-taxane containing chemotherapy had been given in 410 patients by 2.174 cycles and they developed 12 non-neutropenic infections ($p = 0.001$).

Conclusions: The majority of the patients of the two latter groups were non-lymphopenic. In conclusion, the use of docetaxel is associated with increased incidence of non-neutopenic infections. Lymphopenia and low CD4 and CD8 cell counts seem to be the main predisposing factor.

1467 POSTER

Treatment of febrile neutropenia with ceftriaxone monotherapy – Analysis of risk-factors

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Purpose: There are no exactly defined recommendations for single-agent antibiotic treatment because a clear definition of low risk febrile neutropenia is lacking. We analyzed safety and efficacy of ceftriaxone monotherapy in febrile neutropenia (FN).

Methods: In a prospective study we analyzed 959 febrile eps. from 48 hospitals between 2/92 and 1/96. Inclusion criteria: neutropenia (ANC < 1000/ml) with fever (≥38.5°C) or CRP > 1 mg/dl and suspected infection. 901 eps (acute leukemia n = 396, lymphoma n = 220, solid tumors n = 272, others n = 13) with 828 pts aged between one and 97 years were analyzed, of which 876 eps. were evaluable for response. All pts. initially received empirical ceftriaxone treatment (adults: 2 g/day; children: 80 mg/kg/day), either alone (n = 376) or in combination with other agents (n = 525).

Results: Mean ANC was 423/ml (SD ± 316), median duration of neutropenia 10 days. Of 376 eps. treated initially with ceftriaxone alone, 70.8% responded vs. 56.9% in the combination therapy group. The favorable response to the initial monotherapy treatment was achieved within a low-risk population. A low risk was associated with a Karnofsky-Index (KI) > 6 ($p < 0.0001$), ANC ≥ 500/μl ($p = 0.0001$) and a duration of ANC < 5 days ($p < 0.05$) which were significantly more frequent in the monotherapy arm at commencement of treatment. Mortality of FN with ceftriaxone monotherapy was low (1.1%) and contributed to MDI in one eps only (coag.-neg staphylococci).

Conclusion: A KI > 6, an ANC ≥ 500/ml, and a duration of ANC < 5 days predicted a low risk at commencement of antibiotic treatment. Ceftriaxone alone was safe and effective in FN characterized with a low-risk profile.

1468 POSTER

Improvement of ultrasound with digital documentation in cancer patients

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Purpose: Ultrasound (US) is a sensitive diagnostic tool for screening and follow-up of abdominal, cervical and axillary lesions in cancer patients (pts). Sensitivity of ultrasound can be comparable to CT-scan, however, reliability of ultrasound differs intra- and inter-individually. For an improvement in comparison, we studied digital documentation of ultrasound pictures in cancer pts in a prospective study.

Methods: By video signal transmission all US pictures were transmitted to a PC (Pentium processor, 133 MHz, hard disc 2.1 GB, optical disc as a supportive storage medium) to document all US pictures by the SonoWin system (MESO GmbH, Mittweida, Germany).

Results: From November 96 to January 99, 4058 US examinations were performed in 1294 pts. (NHL 19.5%, M. Hodgkin 6.6%, solid tumors 21.9%, AML 8.1%, ALL 2.7%, CML 5.0%, others 36.2%). Ultrasound reexaminations were performed 727 pts (median 5, range 2 to 26) in the follow-up or under current therapy. Reexaminations were performed for comparison of lymph node enlargement, metastatic liver lesions, or for diagnosis of complications of cancer treatment, eg venous thrombosis, chronic-systemic candidiasis or veno-occlusive disease. A total of 20728 ultrasound pictures were archived on a hard disc (magneto-optical disc). Computer assisted documentation improved ultrasound quality, since archived US pictures were directly comparable to real time examinations. Expensive video-print pictures were no longer necessary for documentation. Using basic masks for ultrasound examination reports, time of documentation was shortened, which resulted in considerable material as well as personal costs cost savings for documentation.

Conclusion: Computer assisted digital documentation of ultrasound pictures improves the quality of ultrasound examinations in cancer patients.

1469 POSTER

The validation of the Edinburgh Postnatal Depression Scale (EPDS) as a screening tool for depression in patients with advanced cancer

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Introduction: Screening tools are used in clinical and research settings as a means of detecting depression. The Edinburgh Depression scale (EPDS), a 10 items scale, has been widely used in the assessment of depression in the post natal period and contains questions on subjective sadness and hopelessness which are thought to also be discriminatory for depression in patients with advanced cancer.

Method: Patients with advanced metastatic disease were invited to complete the Edinburgh Depression scale. Patients were also interviewed using the Present State Examination.

Results: 100 patients (age range 25–60 years) mean age 57.2 years and median survival 34 days were recruited into the study. The prevalence of depression by PSE criteria was 22%. The Edinburgh scale had a low rate of mis classification of depression and was found to be acceptable by all patients. A threshold of 10 had a sensitivity of 100%, but a specificity of 79% and a positive value of 53% – 27% of patients scored above this threshold.

Conclusions: This study suggests that the EPDS may be a useful screening tool for depression in patients with advanced disease and may be also be appropriate when assessing psychological well being in clinical trials.

1470 POSTER

Evaluation of informed consent in cancer patient: Émotional aspects and effects of communication

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Purpose: In France, clinical research is regulated by law since 1989. This law requires complete information of those participating in research as well as their written consent. In this setting, the doctor-patient relation can be modified.

We set up this study in order to analyze the cognitive and emotional effects of the information given before consent in cancer patients.

Methods: Patients with metastatic disease who were candidates for therapeutic trials were concerned. Different questionnaires and interviews were proposed to the patients who had informed consent. HADS (Hospital Anxiety and Depression Scale) and WOC-CA (Ways of Coping Inventory) were used to investigate the emotional aspects and patterns of coping.

Results: 120 patients were included during a 16 month period (10 patients refused to participate). An interim analysis on the initial 38 patients was performed: Emotional aspects were consistent with those expected in this population (27% with a HADS score > 15). 70% juged their disease as "serious" but only 50% were aware of the site of the initial tumor. 82% expected a cure of their disease but 55% of the patients did not ask their doctor about the potential results of treatment.

A final analysis will be done and correlations between quality of informed consent and patterns of coping will be analysed. Results will be available in July 99.

Conclusion: Few data are available on the effects of informed consent. These results will be helpful in the future, to help investigators in communicating with their patients for informed consent. Moreover, this should improve the understanding and the decision making of the candidates to therapeutic trials.

1471 POSTER

The critical first 7 days after catheterization

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Purpose: Central venous catheterization (CVC) is essential in the treatment of cancer patients. The time course of catheter-related thrombosis (CRT) during long-term catheterization is not well-known. Therefore the dynamics of CRT formation and evolution was studied over a 6 month period in rats.

Methods: A silicon catheter was placed in the anterior caval vein (AVC) of 54 rats. After in situ fixation at scheduled intervals (1 day to 6 months) thrombosis was studied on semi-serial histology sections by means of LM and SEM and TEM.

Results: Two forms of CRT were observed. Peri-catheter thrombosis (PCT), emerging from the jugular vein and surrounding the proximal catheter, was found in 12/12 rats at D1 and D3. After 7 days this PCT was transformed to a cellular collagen tissue: catheter sleeve (CS) by the migration and proliferation of the activated smooth muscle cells from the injured vein wall. A CS was found in 42/42 rats and remained in situ afterwards, but the incidence did not increase after D7 ($p = 0.44$). Mural thrombosis (MT) occurring in the AVC but not surrounding the catheter, was found in a total of 36/54 rats (66%): none at D1, 5/6 at D3, and 31/42 from D7 to M6. The incidence of MT did increase significantly from D1 to D3 ($p = 0.001$), but not after day 7 and later on ($p = 0.81$)

Conclusion: the PCT leads to sleeve formation which remains in the vein. This transformation occurs at D7. The incidence of MT significantly increases from D1 to D3, but not after D7. This may indicate that the first 7 days following CVC are of critical importance for prophylactic strategies.